UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

DAVID L. HOLCOMB, Plaintiff, v. PFIZER, INC. AND DOES 1–100, INCLUSIVE, Defendants.	No. 1:20-cv-01008-ADA-BAM ORDER GRANTING DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS (ECF No. 10) ORDER GRANTING LEAVE TO AMEND PLAINTIFF'S COMPLAINT WITHIN TWENTY-ONE (21) DAYS

I.

Procedural History

Plaintiff David Holcomb filed this action in California state court on April 27, 2020. (*See* ECF No. 1 at 11.) In his complaint, Plaintiff asserts four causes of action against Defendant Pfizer: (1) negligence; (2) breach of express warranty; (3) breach of implied warranty; and (4) strict liability for manufacturing defects, design defects, and failure to warn. (*Id.*) Defendant received a summons on July 16, 2020. (*Id.* at 10.) The next day, Defendant removed this case to the Eastern District of California asserting subject matter jurisdiction under 28 U.S.C. § 1332 (diversity jurisdiction). (*Id.* at 2.) That same day, Defendant filed an answer with a demand for a jury trial. (ECF No. 3.) On December 28, 2020, Defendant filed the instant motion for judgment on the pleadings. (ECF No. 10.) On January 19, 2021, Plaintiff filed a declaration, informing the

Court that he had discharged his counsel and requesting an extension of time to find a new attorney and file an opposition. (ECF No. 15.) Plaintiff requested four more continuances on February 18, 2021, June 10, 2021, January 31, 2022, and March 22, 2022. (ECF Nos. 19, 22, 33, 37.) To date, Plaintiff has not retained counsel and is proceeding in propria persona. On April 22, 2022, Plaintiff filed a one-page handwritten opposition along with 400 pages of medical records. (ECF Nos. 40, 41.) Defendant filed a reply on May 6, 2022. (ECF No. 42.)

II.

Factual Allegations in the Complaint

In the summer of 2018, Plaintiff's primary care physician prescribed him Lipitor. (ECF No. 1 at 13, ¶ 12.) After Plaintiff had taken the drug for five days, his physician told him to discontinue use because Plaintiff's cholesterol levels were not high enough. (*Id.*) Shortly afterwards, Plaintiff was admitted to the hospital where surgeons removed his gallbladder on July 19, 2018. (*Id.*) A year after the surgery, Plaintiff's doctor once again placed him on Lipitor. (*Id.* at ¶ 13.) About a month later, Plaintiff began to feel unsteady on his feet and experienced pain in his legs. (*Id.* at ¶ 14.) Plaintiff went to a health clinic, where a blood draw indicated damage to both his liver and kidneys. (*Id.* at ¶ 15.) Based on these results, hospital staff told Plaintiff to stop taking Lipitor. (*Id.*) Despite complying with these instructions, Plaintiff continued to deteriorate, eventually becoming paralyzed from the waist down and having difficulty moving his arms. (*Id.*) Plaintiff checked into Memorial Medical Center in Modesto, California on August 14, 2019, where doctors diagnosed him with statin induced rhabdomyolysis. (*Id.* at ¶ 16.) Plaintiff's diagnosis had caused muscle deterioration, edema, damage to his liver and kidneys, and an inability to use his extremities. (*Id.*) Plaintiff remained at the hospital for several weeks and continued to undergo treatment after his discharge. (*Id.*)

III.

Legal Standard

"After the pleadings are closed – but early enough not to delay trial – a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). Much like a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a Rule 12(c) motion "challenges the legal sufficiency of

the opposing party's pleadings." *Morgan v. County of Yolo*, 436 F. Supp. 2d 1152, 1154–55 (E.D. Cal. 2006). "Because the motions are functionally identical, the same standard of review" applies to both. *Dworkin v. Hustler Magazine Inc.*, 867 F.2d 1188, 1192 (9th Cir. 1989). Therefore, in considering a party's Rule 12(c) motion, the court "must accept all factual allegations in the complaint as true and construe them in the light most favorable to the nonmoving party." *Fleming v. Pickard*, 581 F.3d 922, 925 (9th Cir. 2009). In this process, the court ignores any conclusory statements and assesses whether the remaining factual assertions allege a plausible claim to relief. *Chavez v. United States*, 683 F.3d 1102, 1108 (9th Cir. 2012) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) and *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. A court must grant a Rule 12(c) motion "when there is no issue of material fact in dispute, and the moving party is entitled to judgment as a matter of law." *Fleming*, 581 F.3d at 925. When considering a Rule 12(c) motion, courts may take judicial notice of facts outside the pleadings pursuant to Federal Rule of Evidence 201. *See Heliotrope Gen., Inc. v. Ford Motor Co.*, 189 F.3d 971, 981 n.18 (9th Cir. 1999).

IV.

Discussion

A. The Court will not consider Plaintiff's medical records.

Plaintiff's opposition to Defendant's motion contains no substantive legal arguments beyond the assertion, "I oppose the motion for summary judgment." (ECF No. 40 at 1.) Rather, the bulk of Plaintiff's filing consists of over 400 pages of medical records from before and after he took Lipitor. (*See id.*) Defendant argues that Plaintiff cannot rely on such extrinsic evidence to defeat a Rule 12(c) motion, which tests the sufficiency of the pleadings rather than the sufficiency of the evidence. (ECF No. 42 at 2.)

Federal Rule of Procedure 12(d) does permit courts to consider matters outside the pleadings, if they provide notice to both parties, thereby converting a Rule 12(c) motion into a motion for summary judgment. *See* Fed. R. Civ. P. 12(d); *R.J. Corman Derailment Servs., LLC v.*

Int'l Union of Operating Eng'rs, Local Union 150, AFL-CIO, 335 F.3d 643, 647 (9th Cir. 2003). Additionally, courts are entitled to take judicial notice of matters outside the pleadings pursuant to Federal Rule of Evidence 201. The Court, however, finds that Plaintiff cannot avail himself of either procedural tool. First, the Court is not inclined to convert Defendant's Rule 12(c) motion based on Plaintiff's unsupported proffer of medical records. Second, Plaintiff's medical records are not of the type that are "generally known" or "accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b); *see also Walker v. Woodford*, 454 F. Supp. 2d 1007, 1022 (S.D. Cal. 2006).

Therefore, the Court declines to consider Plaintiff's medical records for purposes of ruling on Defendant's Rule 12(c) motion.

B. Negligence and Strict Products Liability (Claims 1 and 4)

Plaintiff seeks products liability damages from Defendant under theories of both negligence and strict liability. Because the elements of these claims – and the deficiencies in the complaint – are similar, the Court will address them in tandem. At the outset, the Court notes one organizational aspect about these causes of action.

Plaintiff's negligence cause of action does not specify a particular theory on which he seeks to recover damages. Rather, he alleges that Defendant negligently "designed, manufactured, tested or failed to test, inspected or failed to inspect, packaged, labeled, distributed, recommended, displayed and sold" Lipitor with the knowledge that it was unsafe. (ECF No. 1 at 16, ¶ 25.) Defendant argues that, based on the factual allegations in the complaint, the thrust of Plaintiff's negligence claim is that Defendant failed to warn about the risk of rhabdomyolysis associated with Lipitor. (ECF No. 10 at 12.) Defendant also argues that, to the extent Plaintiff attempts to state a negligent design defect claim, the Court should bar such a claim as a matter of law. (*Id.* at 20, n.7.) Finally, Defendant's argument that Plaintiff has failed to state a manufacturing defect claim logically applies to both negligence and strict liability theories. (*See id.* at 22.) Defendant does not address any other theory of negligence. The Court similarly cannot discern factual allegations to support any other theory of negligence based on the testing, inspection, packaging, distribution, display, or sale of Lipitor. Therefore, the Court will limit its

analysis of both Plaintiff's negligence and strict liability claims to warning defect, design defect, and manufacturing defect theories.

i. Distinguishing negligence and strict liability causes of action in the context of prescription drug products liability cases.

Plaintiffs may seek recovery in products liability actions on theories of both strict liability and negligence. *Merrill v. Navegar, Inc.*, 28 P.3d 116, 124 (Cal. 2001) (quoting *Jiminez v. Sears, Roebuck & Co.*, 482 P.2d 681, 686 (Cal. 1971)). To prove negligence under California law requires a plaintiff to show that the defendant "had a duty to use due care, that he breached that duty, and that the breach was the proximate or legal cause of the resulting injury." *Nally v. Grace Comty. Church*, 763 P.2d 948, 956 (Cal. 1988). In the products liability context, the plaintiff must, therefore, demonstrate that a defect in the defendant's product caused injury and that the existence of the defect was due to the defendant's negligence. *Merrill*, 28 P.3d at 124.

Strict liability differs from negligence in that it focuses on the design of the product rather than the conduct of the manufacturer. *Brown v. Superior Court*, 751 P.2d 470, 474 (Cal. 1988). Therefore, a plaintiff seeking recovery on a strict liability theory need not prove duty or breach of duty. *Brooks v. Eugene Burger Mgmt. Corp*, 264 Cal. Rptr. 756, 764 (Cal. Ct. App. 1989). Rather, the plaintiff must show only that she suffered an injury and that a defect in the product caused the injury. *Id.* Generally, there are three types of defects that allow for recovery under a strict liability theory: manufacturing defects, design defects, and warning defects. *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 553 (Cal. 1991). The rules differ slightly, however, in the prescription drug context. Most significantly, prescription drug manufacturers cannot be held strictly liable for design defects. *Brown*, 751 P.2d at 477. Additionally, strict liability for warning defects applies only when a manufacturer fails to warn about risks that were "either known or reasonably scientifically knowable at the time of distribution." *Id.* at 482–83; *see also Carlin v. Superior Court*, 920 P.2d 1347, 1354 (Cal. 1996). These rules do not impact a plaintiff's ability to sue under a strict liability manufacturing defect theory or under general principles of negligence. *See Brown*, 751 P.2d at 483, n.12; *see also Scott v. C.R. Bard, Inc.*, 180 Cal. Rptr. 3d 479, 489 (Cal. Ct. App. 2014) (recognizing the existence of a negligent design

defect cause of action in prescription drug cases).

ii. Warning defect

1. Plaintiff fails to allege both breach of duty and causation.

Plaintiff alleges two main injuries resulting from Defendant's failure to warn: (1) the removal of his gallbladder, and (2) his diagnosis of rhabdomyolysis. Defendant argues that Plaintiff's rhabdomyolysis claim fails under both negligence and strict liability theories because the complaint fails to allege a breach of duty and causation. (ECF No. 10 at 15–16.) Regarding Plaintiff's gallbladder surgery allegation, Defendant argues that the complaint fails to allege that Lipitor caused Plaintiff's injury. (*Id.* at 14, n.3.)

To state a negligent warning defect claim, a plaintiff must allege that the defendant failed to warn of known risks about which a reasonably prudent manufacturer would have warned. *Carlin v. Superior Court*, 920 P.2d 1347, 1351 (Cal. 1996). Under a strict liability theory, a plaintiff need not allege a breach of duty, but must show that the "defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." *Id.* In both cases, courts consider the adequacy of prescription drug warnings by regarding the physician, rather than the patient, as the recipient. *See Brown*, 751 P.2d at 477–78, 481; *Carmichael v. Reitz*, 95 Cal. Rptr. 381, 400 (Cal. Ct. App. 1971). Therefore, a complaint will not demonstrate proof of causation "if stronger warnings would not have altered the conduct of the prescribing physician." *Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659, 661 (9th Cir. 2004); *see also Tapia v. Davol, Inc.*, 116 F. Supp. 3d 1149, 1158 (S.D. Cal. 2015).

To the extent that Plaintiff claims Defendant failed to provide any warnings about the risk of rhabdomyolysis, this allegation cannot be true. Defendant has provided copies of the FDA-approved labels for Lipitor from 2017, 2018, and 2019, which repeatedly mention the risk of rhabdomyolysis.[1] Assuming that Plaintiff's argument is that Defendant's warnings about

[1] The Court grants Defendant's unopposed request to take judicial notice of the Lipitor labels, but only for the purpose of noting the existence of, rather than ruling on the adequacy of, warnings about rhabdomyolysis. *See* Fed. R. Evid. 201(b)(2) (court may take judicial notice of a fact that is not subject to reasonable dispute because it "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned."); *see also In re Epogen & Aranesp Off-Label Marketing & Sales Practices Litigation*, 590 F. Supp. 2d 1282, 1286 (C.D. Cal. 2008)

rhabdomyolysis were inadequate, that claim also fails. At one point, the complaint alleges that "DEFENDANTS were aware of high rate of unexplained failures of Lipitor but did not provide this information to PLAINTIFF or PLAINTIFF's physicians." (ECF No. 1 at 14, ¶ 17.) The complaint does not, however, explain what these failures were or when they occurred. It also fails to allege how Defendant might have altered Lipitor's label to warn about those failures. Finally, it provides no information about how knowledge of those failures would have changed Plaintiff's physician decision to prescribe. Without this information, the Court cannot discern a breach of Defendant's duty to Plaintiff's physician. Nor can it find that inadequate information in Lipitor's label was the cause of Plaintiff's injuries.

Plaintiff's complaint is also deficient to the extent that it draws a connection between his use of Lipitor and his gallbladder surgery. While the Court cannot identify any warnings in Lipitor's label regarding the risk of gallbladder surgery, Plaintiff nevertheless fails to allege that any defect in Lipitor caused his injury. Plaintiff alleges that, shortly after taking Lipitor for five days in 2018, he underwent surgery to have his gallbladder removed. (ECF No. 1 at 13, ¶ 12.) The complaint goes on to allege, "It was not identified to PLAINTIFF that Lipitor contributed to the need for his gallbladder removal until after August of 2019." (*Id.*) These allegations are insufficient to bridge the gap between correlation and causation. Plaintiff provides no information about how he discovered a link between Lipitor and gallbladder surgery or whether that risk was known or scientifically knowable at the time Plaintiff took Lipitor in 2018.

2. Plaintiff has not pleaded facts sufficient to survive Defendant's pre-emption defense.

Defendant argues that Plaintiff's warning defect claims fail for an independent reason: federal law pre-empts them. (ECF No. 10 at 16–19.) Specifically, Defendant argues that, assuming it had a duty under state law to alter Lipitor's label, it could not have done so without violating federal law. (*Id.* at 18.)

When it is impossible for a private party to comply with both federal and state law, federal law prevails. *See* U.S. Const., Art. VI, cl. 2; *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 480

(taking judicial notice of FDA-approved label for prescription drug Epogen.)

(2013). This risk of pre-emption can arise in the context of prescription drug labeling, where state tort law and federal regulations sometimes create conflicting duties for drug manufacturers. Specifically, the Federal Drug Administration ("FDA") must approve the language in a prescription drug's label before a manufacturer can place that drug on the market. *Wyeth v. Levine*, 555 U.S. 555, 567–68 (2009). Once a prescription drug hits the market, manufacturers typically need approval from the FDA before changing the label. *Id.* at 568. There is, however, an avenue – called the "changes being effected" ("CBE") process – by which manufacturers can make certain labeling changes without pre-approval from the FDA. *Id.* The CBE process permits manufacturers "to add or strengthen a contraindication, warning, precaution, or adverse reaction" reflecting "newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii)(A). "Newly acquired information" includes both new data as well as updated analyses of data that the manufacturer had previously submitted to the FDA. *Wyeth*, 555 U.S. at 569. While a manufacturer does not need pre-approval to use the CBE process, the FDA retains the authority to reject label changes made through that process. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019) (citing 21 C.F.R. § 314.70(c)(6), (7)).

A pre-emption issue arises when a plaintiff alleges the inadequacy of a prescription drug's label, requiring alterations under a state tort warning defect theory, but fails to demonstrate newly acquired information that would permit a manufacturer to make unilateral changes to a drug's label under FDA regulations. In that case, it would be impossible for a manufacturer to comply with both state and federal law. Nevertheless, "[i]mpossibility pre-emption is a demanding defense." *Id.* at 573. Therefore, once a plaintiff alleges newly acquired information, courts will find pre-emption only if the manufacturer demonstrates that there is "clear evidence" the FDA would not have approved a label change through the CBE process. *Id.* at 571. " '[C]lear evidence' is evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Albrecht*, 139 S. Ct. at 1672. Whether federal law pre-empts state law warning defect tort claims is a question of law. *Id.* at 1679. Despite the fact-specific nature of the pre-emption

inquiry, courts have found it permissible to decide the question on the pleadings. *See, e.g., Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 672 (S.D.N.Y. 2017); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 42–43 (1st Cir. 2015); *but see Evans v. Gilead Sciences, Inc.*, No. 20-cv-00123-DKW-KJM, 2020 WL 5189995 at *10–*11 (D. Haw. 2020 Aug. 31, 2020) (holding that it is inappropriate to rule on a federal pre-emption affirmative defense before summary judgment).

The Court agrees with Defendant that Plaintiff has failed to allege sufficient facts in his complaint to demonstrate that Defendant could have used the CBE process to change Lipitor's label. The extent of the newly acquired information Plaintiff alleges is a "high rate of unexplained failures of Lipitor." This allegation does not describe the type of failures about which Defendant knew. Nor does it articulate whether those failures were related to rhabdomyolysis or gallbladder surgery. Plaintiff also fails to define what a "high rate" of failure means. The ambiguity of Plaintiff's allegation does not lead to a reasonable inference that Defendant had newly acquired information to make a labeling change through the CBE process.

3. The Court will decline to find that Lipitor's label is adequate as a matter of law.

Defendant urges the Court to dismiss Plaintiff's warning defect claims by finding that Lipitor's FDA-approved label is adequate as a matter of law. (ECF No. 10 at 12–15.) Given the lack of briefing in this case, the Court declines to address this argument at this time. Rather, due to the factual deficiencies in the complaint, the Court will dismiss Plaintiff's strict liability and negligence warning defect claims without prejudice.

iii. Design defect

As discussed above, Plaintiff cannot make out a strict liability design defect claim because California law prohibits it. *Brown*, 751 P.2d at 477. Defendant urges this Court to extend *Brown*'s holding to preclude Plaintiff from pursuing a negligent design defect claim. (ECF No. 10 at 20, n.7.) As Defendant concedes, however, California courts have held that *Brown*, while barring strict liability design defect claims against prescription drug manufacturers, did not limit a plaintiff's ability to pursue negligence claims. *See Scott*, 180 Cal. Rptr. 3d at 489. In light of this

precedent, the Court declines Defendant's invitation to create a per se bar against bringing negligent design claims under California law.

Defendant's alternative ground for dismissing Plaintiff's negligent design claim – that federal law pre-empts it – meets with greater success. As discussed above, when it is impossible for a party to comply with both state and federal law, federal law prevails. *Bartlett*, 570 U.S. at 480. To state a claim for negligent design in California, a plaintiff "must identify what aspect of [a product] makes it defective." *Marroquin v. Pfizer, Inc.*, 367 F. Supp. 3d 1152, 1164 (E.D. Cal. 2019). Determining whether a manufacturer should be liable for a given defect requires the factfinder to balance the product's likelihood of causing harm and the gravity of that harm against the burden of precautions that would avoid the harm. *Merrill*, 28 P.3d at 125 (quoting *Pike v. Frank G. Hough Co.*, 467 P.2d 229, 232 (Cal. 1970)). Even when a plaintiff identifies a specific defect, however, federal regulations make it impossible for manufacturers to make "major changes" to a prescription drug in response to a state law risk/benefit balancing test without pre-approval from the FDA. *Bartlett*, 570 U.S. at 477 (quoting 21 C.F.R. § 314.70(b)(2)(i)) ("Once a drug – whether generic or brand-name – is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'"). Federal law does permit manufacturers to make certain moderate or minor changes to a drug without prior approval from the FDA. *See* 21 C.F.R. 314.70(b)–(d); *Evans*, 2020 WL 5189995 at *10.

Plaintiff does not identify a particular defect that caused either his rhabdomyolysis or gallbladder surgery. If it is, for example, a defect in Lipitor's chemical composition, federal law will necessarily pre-empt Plaintiff's claim. On the other hand, if it is a defect that would require only a moderate or minor change under federal law, Defendant's pre-emption defense may fail. The Court has serious doubts that Plaintiff will be able to cure his negligent design claim to survive Defendant's pre-emption defense. Given the lack of specific factual allegations in the complaint, however, the Court simply cannot make that determination at this time. Therefore, while the Court must dismiss Plaintiff's strict liability design defect claim with prejudice, it will dismiss Plaintiff's negligent design claim without prejudice.

iv. Manufacturing defect

A manufacturing defect exists when a product "differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 454 (Cal. 1978). To succeed on a manufacturing defect claim, under both negligence and strict liability theories, a plaintiff must allege how the product in question differed from its intended design. *Marroquin*, 367 F. Supp. 3d at 1164; *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1155 (E.D. Cal. 2010). The Court agrees with Defendant that Plaintiff's complaint contains no allegations regarding how the doses of Lipitor he consumed differed in any way from others that Defendant produced. Therefore, the Court will dismiss both Plaintiff's strict liability and negligence manufacturing defect claims without prejudice.

C. Breach of Warranty (Claims 2 and 3)

Defendant argues that, because Plaintiff has failed to state a warning defect or manufacturing defect claim, his breach of warranty claims must fail as well. (ECF No. 10 at 23.) Additionally, Defendant argues that Plaintiff's express warranty claim fails because he failed to allege any statements on which Plaintiff's physician relied when prescribing Lipitor. (*Id.*)

A breach of express warranty arises when a product's performance does not conform to the seller's promises. *Brown*, 751 P.2d 470, 484 (citing Cal. U. Com. Code § 2313(1)(a)). Implied warranties arise not through statements of the seller but through the contract itself, by operation of law. *Hauter v. Zogarts*, 534 P.2d 377, 385 (Cal. 1975). Under California law, every contract contains an implied warranty that a seller's goods will be "merchantable." Cal. U. Com. Code § 2314(1). Additionally, an implied warranty of fitness for a particular purpose attaches when the seller "has reason to know that a buyer wishes goods for a particular purpose and is relying on the seller's skill and judgment to furnish those goods." *Martinez v. Metabolife Int'l Inc.*, 6 Cal. Rptr. 3d 494, 500 (Cal. Ct. App. 2003); *see also* Cal. U. Com. Code § 2315. In the context of prescription drugs, manufacturers are not liable for breach of warranty based on defects that were unknown or not scientifically knowable at the time of distribution. *Carlin*, 920 P.2d at 1355. Additionally, the physician, not the patient, stands in the place of the "ordinary consumer" to whom the manufacturer directs warranties. *Id.*

The Court agrees with Defendant that Plaintiff's breach of warranty claims must be dismissed. First of all, Plaintiff does not allege any specific warranties regarding gallbladder surgery, and the complaint fails to make a causal connection between Plaintiff's gallbladder surgery and his use of Lipitor. Therefore, the Court cannot find that the complaint alleges any breach of warranty, express or implied, about the risk of suffering gallbladder injuries.

Additionally, to the extent that Plaintiff's breach of warranty claims concern his rhabdomyolysis diagnosis, the Court disagrees that Plaintiff has failed to allege that Defendant made express warranties. The complaint states that Defendant "utilized advertising media to urge the use and consumption of Lipitor and expressly warranted to PLAINTIFFS and other members of the general public that Lipitor was effective, proper, and safe for its intended use." (ECF No. 1 at 16, ¶ 31.) Plaintiff also obliquely alleges that both he and his physician relied on Defendant's express warranties. (*Id.* at 17, ¶ 32.) Nevertheless, the existence of Lipitor's FDA-approved label requires Plaintiff to be more specific about the statements upon which he and his physician relied. For example, if Defendant made claims that Lipitor had no side effects, contrary to the information in the label, that could support a claim for breach of warranty, if Plaintiff's physician relied on those statements. Absent such a statement – and given the fact that the label explicitly warns about the risk of rhabdomyolysis – Plaintiff must allege how the label was inadequate, in light of known or knowable risks, in order to state a claim for breach of express warranty. Under California law, this failure to allege how Lipitor's label was inadequate in light of known or knowable risks also forecloses Plaintiff's ability to pursue his implied warranty claims.

Based on this analysis, the Court will dismiss Plaintiffs implied and express warranty claims without prejudice.

D. Leave to Amend

Generally, "[c]ourts are free to grant a party leave to amend whenever 'justice so requires,' and requests for leave should be granted with 'extreme liberality.'" *Moss v. U.S. Secret Serv.*, 572 F.3d 962, 972 (9th Cir. 2009). In fact, a court should grant leave to amend, even absent a request, unless it determines that a plaintiff cannot cure the deficiencies in the complaint. *Ebner v. Fresh, Inc.*, 838 F.3d 958, 963 (9th Cir. 2016) (quoting *Doe v. United States*, 58 F.3d

494, 497 (9th Cir. 1995)). There are several factors a district court considers when deciding whether to grant leave to amend: undue delay, the movant's bad faith or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party, and futility. *Brown v. Stored Value Cards, Inc.*, 953 F.3d 567, 574 (9th Cir. 2020) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)). Of these factors, the court should particularly consider prejudice to the opposing party. *Id.*; *Eminence Cap., LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003).

Here, the Court finds that Defendant's Rule 12(c) motion addresses Plaintiff's initial complaint and that it would not be futile to afford Plaintiff an opportunity to amend all claims – except for the strict liability design defect cause of action – in light of the rulings in this order. There is also no evidence that Plaintiff's cause is motivated by bad faith. Finally, regarding the first and fourth factors, the Court recognizes that this matter was filed over two years ago, and that Defendant filed its motion for judgment on the pleadings on December 28, 2020. The substantial delay in this case has likely prejudiced both parties, but that delay is attributable to the Court alone. The Court cannot permit its overcrowded docket to result in the dismissal, with prejudice, of potentially meritorious claims. Plaintiff will, therefore, be granted leave to amend the complaint to address the deficiencies noted in this order.

Accordingly,

1. Defendant's motion for judgment on the pleadings, (ECF No. 10), is granted;
2. Plaintiff's strict liability design defect claim is dismissed, with prejudice;
2. All other in Plaintiff's complaint are dismissed, without prejudice;
3. Plaintiff is granted leave to amend his complaint within twenty-one (21) days of service of this order.

IT IS SO ORDERED.

Dated: December 14, 2022

UNITED STATES DISTRICT JUDGE